

FDA review of safety and efficacy that all new drugs must undergo. This partial restoration of patent term—up to five years in certain circumstances when such restoration would not result in a greater than 14 year effective patent life—allowed pioneer drug firms additional time to recoup the enormous investments required to bring a new drug to market. This helped attract the investment capital that pioneer firms need to develop the next generation of life-saving drugs.

Consumers benefit from this win-win dynamic because the American public gets both new drugs and competitively priced off-patent medications.

As we start the 15th year since the enactment of this important health and consumer law, we have a generic pharmaceutical sector that has developed into an integral part of the health care system, which together with innovator pharmaceutical and biotechnology companies lead the world in the development and marketing of new health care products.

While I think that the track record of the Hatch-Waxman Act is enviable, I hope that we can even do better for the American public in the future.

Accordingly, I intend to devote time during the next Congress to begin the necessary examination into how we can make changes in the law that will increase our ability to produce both the innovative products that we have come to expect and the lower priced generic products that are so attractive to the family budget.

I intend for this examination to include a serious study of how well the Drug Price Competition and Patent Term Extension Act has functioned over the past 14 years, whether the Act has fulfilled its initial promise, how the courts have interpreted the Act, and indeed, how it has been implemented. I hope to work closely in this endeavor with my good friend and colleague Senator JIM JEFFORDS, Chairman of the Labor and Human Resources Committee, which shares jurisdiction over the Act with the Judiciary Committee.

A major test of such a review will be to assemble a package of initiatives that will retain the delicate but essential balance between the innovator and generic sectors of the industry. This will be a difficult task but it is a worthwhile endeavor for the American people.

Even during this session of Congress, some have proposed changes to our nation's drug discovery laws. There has, for example, been some discussion about changing one of the most controversial provisions of the 1984 law—the so-called Bolar Amendment. Section 271(e) of the Title 35, contains language to overturn a 1984 Federal Circuit Court of Appeals ruling in the case of *Roche v. Bolar Pharmaceutical Co.*, which held that conducting the tests required to secure approval of generic copies of pioneer drugs constituted patent infringement. Section 271(e)(1) es-

tablishes an exception to patent infringement laws to authorize generic pharmaceutical companies to conduct testing on patent approved pharmaceutical products for purpose of filing an abbreviated new drug application.

Recently, the application of section 271(e)(1) has been a matter of some controversy in an on-going legal battle between two pioneer drug firms, one company holding existing patent protection and FDA product approval and the other company asserting its own patent rights and seeking pioneer rather than generic approval from FDA. While ultimately the courts must decide whether this is a case of patent infringement, it is clear that this is not merely a simple, garden variety patent infringement case because it also raises the question of precisely what type activities that section 271(e)(1) should allow, and should not allow, in the context of developing not only generic drugs but new drugs and biologicals that they potentially compete directly with.

While I do not take a position on the merits of the actual patent rights in dispute in the current *Amgen v. Hoechst Marion Roussel* litigation, I must say this case is of some concern to me, especially with regard to court's initial findings which are not consistent with, and broaden, Congress' intent in enacting 271(e).

I do believe Congress would be wise to reassess the breadth of section 271(e)(1) in light of this and a number of court decisions since 1984 that have tended to expand the scope of this provision. One case in particular is the 1990 Supreme Court decision in *Lilly v. Medtronic*.

My position on these questionable decisions has been clear for some time. I was, in fact, a signatory to an amicus brief in the *Lilly* case that argued for a somewhat narrower interpretation of 271(e)(1) than has evolved in the courts.

One proposal worthy of serious consideration is to more clearly limit the applicability of 271(e)(1) to exclude testing and other activities necessary for approval of NDAs and BLAs from the patent infringement exemption. Of course, the 271(e)(1) question is only one of many issues that will undoubtedly be proper for further discussion in the next Congress.

Some are concerned about whether drugs that were already in FDA review at the time of enactment of Hatch-Waxman (the "pipeline drugs") have received adequate and fair patent protections in view of subsequent delays that were encountered. Congress should undertake complete review of this proposal during our study of Waxman-Hatch next year, as I believe the evidence will show that there are inequalities we should take steps to remediate.

Others are concerned about the application of the 180 day generic drug exclusivity rule in the aftermath of the *Mova* decision. Indeed, some are advocating report language that will give

FDA new leeway to adopt a "first-to-succeed" in patent litigation approach rather than the "first-to-file" an ANDA that the courts have found.

Frankly, I have concerns about the current outcome whereby some ANDA applicants appear to be handsomely rewarded by pioneer firms for not selling generic competitors.

Still others advocate in the spirit of international harmonization adopting the European rule of a 10 year marketing exclusivity period for all new drugs. And others point out that the advent of the new GATT-required 20 year from filing patent term may change the traditional incentives in coordinating PTO and FDA approvals.

It is time, some argue, to do away completely with current rule by which only 5 years of patent life may be restored to compensate time lost at FDA and only if the effective patent term does not exceed 14 years. Some would also like to revise the rule that limits patent restoration for time lost during the IND phase in a for each 2-days lost, 1-day restored ratio.

On the generic side of the industry, there is concern that as NDA approvals speed up due to user fees, generic approvals continue to lag and take much longer than NDAs. There is also great frustration about what some describe as challenges to the bioequivalence of generic products that are more a delaying and harassing tactic than a bona fide scientific dispute.

And then, there are those in the generic industry who believe that FDA's Orange Book, which records the patents in effect for FDA approved drugs, should be renamed as the "Evergreen Book"!

So there are many issues that merit consideration as we reassess the adequacy of the laws pertaining to the generic and pioneer sectors of the pharmaceutical industry.

Our focus should be on ascertaining what steps we can take that will most benefit the American people in terms of providing incentives both for the development of new drugs and the production of competitively priced generic products. This has and will continue to require a delicate balance. There is an inherent tension between the twin goals discovering the next generation of drugs while at the same time providing generic versions of today's medications.

My goal is to reconcile these somewhat conflicting but wholly meritorious goals in the interest of the American people, and I look forward to working with my colleagues in the House and Senate on this complex issue next year.

TRIBUTE TO ALLEN GARTNER

Mr. LEAHY. Mr. President, Allen Gartner is one of Vermont's real citizen treasures. He was recently honored by the Rutland Region Chamber of Commerce on their 100th anniversary. I ask unanimous consent that a letter I

wrote and an article about this honor be printed in the RECORD.

The whole Gartner family represent the best of Vermont and Marcelle and I value their friendship.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

PATRICK LEAHY,
U.S. SENATOR,
October 1, 1998.

RUTLAND REGION CHAMBER OF COMMERCE,
North Main Street,
Rutland, VT

DEAR FRIENDS: My mother was wrong. She always told me that if I wanted something done right, I should do it myself.

What I learned a little later in life was that if I REALLY wanted something done right, I needed to ask Allen Gartner to do it.

Allen personifies Rutland—his love of his family, his sense of the broader community, his deep spirituality, and his sense of the broader community of which we are all a part. Most important for his friends in Rutland and all over Vermont is an indomitable sense that if you work hard enough, and if your cause is just, anything is possible.

It is fitting that Allen is honored by a group as respected as the Rutland Region Chamber of Commerce. But Allen, by the life he leads, the work he does and the joy he brings to others, honors all of us every single day.

Sincerely,

PAT.

[From the Rutland Daily Herald, October 5, 1998]

ALLEN GARTNER, BUSINESS LEADER WITH A SENSE OF CHARITY

(By Laurie Lynn Strasser)

"Tzedaka" is the most important word in the Hebrew language, Mintzer Brothers co-owner Allen S. Gartner said last Thursday after receiving the 1998 Business Person of the Year award from the Rutland Region Chamber of Commerce.

It means "charity."

"I was raised that this is the greatest country in the world, by a long shot," said Gartner. "It was our obligation to give back to the community. My parents not only spoke those words, but they lived by those words."

In conferring the honor, Rutland Chamber of Commerce Executive Vice President Tom Donahue rattled off a litany of boards that Gartner has served on. Donahue added that if he listed all the extracurriculars and charities Gartner had helped, "this luncheon might turn into a dinner meeting."

In an interview afterward, Gartner said he felt honored by the award, but that recognition was not the point.

"Whatever I'm doing, I need to do because that's what people should do," he said. "The bottom line of business is not what's important. That's not what we're on this planet for. We're only here a speck anyway. Really, it's just a blip. What's important is the welfare of the community." His father, the late Walter Gartner, used to say that the best form of giving is anonymous. His father made it out of Nazi Germany in the nick of time, but lost the rest of his family to the Holocaust. After World War II, he married and bought Mintzer Bros., a fuel oil and grain business that had been founded in 1926.

Walter Gartner's wife, Margot, gave birth to Edward in 1945 and Allen in 1949.

The younger Gartner still recalls the days when customers bought berry baskets, syrup cans and laying mash. By the early 1960's, the emphasis had switched to building supplies.

Gartner worked at the Strongs Avenue store in the summers between his graduation from Rutland High School in 1967 and Union College in 1971.

He spent his junior year abroad in France. Just last year, he returned to Paris for an emotional reunion with his host family. The people he last saw as teenagers are now in their 40s, he noted.

Gartner earned a bachelor's degree in political science and modern languages.

"I have a passion for politics," he said. "To me, politics is conflict and compromise."

He went on to pursue an advanced degree at New York University Law School, although he never intended to become a practicing attorney.

"I spent the first 20 years of my life trying to be a peace-maker," he said. "The first day of law school, the professor's asking, 'What would your argument be? It was always antithetical to what I believed, but it was good education. I refer to my law school education almost every day of the week.'"

It wound up taking him seven years to finish at NYU because his father had suffered a stroke. Living with relatives on Manhattan's Upper West Side, he would attend graduate school then work for one semester each year.

"I'd go down to the pay phone in the basement of the law school library and make phone calls for the business," he recalled. "I'd do this every day, buying and selling lumber, calling customers."

Gradually, he and his brother, Edward, took the reins from their father. Walter Gartner died in 1983.

The brothers opened another Mintzer branch in Ludlow in the early 1980s. Three years ago they expanded again into the Route 7 south space vacated by Grossman's after it went out of business.

In the coming year, Mintzer Bros. may face its toughest challenge in 70 years. Home Depot, the largest hardware chain in the world, has indicated an interest in opening a large store in Rutland.

"Big orange is a dose of reality," he said referring to Home Depot's theme color. "You've got to fight the good fight, fight it as best as you can. Business today is war. I'm not sure I'm cut out for war."

Gartner was instrumental in recruiting area merchants to form Rutland Region First, a grassroots organization whose goal is to stop Home Depot from locating in the area.

No matter what happens with the business, it is important to keep perspective, said Gartner. He has faced worse hardships, including the loss of his firstborn daughter when she was six days old and chronic back pain for the past 17 years. Financial challenges are not as important as keeping his family intact, Gartner said.

Just like when he was growing up, Gartner still plays the role of peacemaker, but these days he has taken the quest to an international level.

Last week, he met Palestinian leader Yasser Arafat, who was in Washington, DC, to parley with Israeli Prime Minister Benjamin Netanyahu.

"It pains me to see Palestinians mistreated," he said. "I'm a Zionist, but I think we've got to live together."

Committed to the Middle East peace process for the past decade, he shaved off his beard when he learned of the historic 1979 accord between Israel and Egypt. When Yasser Arafat signed a treaty with the late Isaac Rabin in 1993, Gartner was there on the south lawn of the White House.

"It was a most emotional moment for me," he recalled, describing weeping Jewish and Arab Americans throwing their arms around each other.

RECOGNITION OF MARY LOUISE SINCLAIR

Mr. SPECTER. Mr. President, I have sought recognition to honor a special member of my staff who is retiring from government service at the end of the 105th Congress.

Mary Louise Sinclair has served with loyalty and with distinction in the United States Senate family for nearly 36 years. During the course of her service in the Senate, Mary Louise has worked for some notable members of this body. She has worked for Senator Everett Dirksen as a secretary from 1962 to 1970. She then joined the staff of Senator Robert Taft as the office manager and secretary, where she stayed for his full term until 1977. My fellow Pennsylvanian, the late Senator John Heinz, was also privileged to have Mary Louise on his staff as a special assistant for a remarkable 13 years from 1978 to 1992, and since 1993, Mary Louise has served with distinction as my Executive Secretary.

Through her dedication and diligence, Mary Louise has enabled me to maximize my efficiency to ensure that I am in the best position to represent Pennsylvania. For that, my staff, my constituents, my family and I are very grateful.

I applaud her service and offer her, on behalf of my Senate colleagues, our goodwill and best wishes upon her retirement.

RECOGNITION OF STAFF

Mr. SPECTER. Mr. President, I would also like today to recognize the efforts of my staff in my personal office and State offices, who help me each day in responding to the needs of 12 million Pennsylvanians and countless other Americans who write, call or visit. I have long said that I believe I have the best staff in the Senate, and I want to convey my appreciation publicly for the work they do on behalf of the taxpayers.

Thus, as the work of the 105th Congress comes to a close, I extend my thanks to David Urban, Gretchen Birkle, Molly Birmingham, Kristin Bodenstedt, Jane Brattain, David Brog, Mark Carmel, Allison Cooper, Juliette Cox, Alli DeKosky, Aura Dunn, Jeff Gabriel, Cathy Gass, David Grindel, Peter Grollman, Patricia Haag, Andrea Haer, Alegra Hassan, Kevin Mathis, Pam Muha, Anthony Pitagno, Dan Renberg, Charlie Robbins, Jill Schugardt, Mary Louise Sinclair, Seema Singh, Erin Streeter, Jim Twaddell, John Ulliot, Ron Williams, and Chris Wilson of my Washington office.

Similarly, I appreciate the efforts of my Pennsylvania-based staff, which includes Ken Braithwaite, Mary Clark, Anthony Cunningham, Patty Doohan, Kenny Evans, Carmen Santiago, Banita Sharma, Gil Stein, Bella Straznik, Corene Ashley, Stan Caldwell, Katherine Risko, Doug Saltzman, Salena